

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

GP1632#  
VM 7-05-00  
#B

Applicant: HADLACZKY et al.

Serial No.: 09/096,648

Filed: June 12, 1998

For: ARTIFICIAL CHROMOSOMES,  
USES THEREOF AND METHODS  
FOR PREPARING ARTIFICIAL  
CHROMOSOMES

Art Unit: 1632

Examiner: Martin, J



I hereby certify that this paper and the attached papers are being deposited with the United States Postal Service as First Class Mail in an envelope addressed to:

Assistant Commissioner for Patents  
Washington, D.C. 20231, on this date.

6/19/00  
Date

Paula Schoeneck  
Paula Schoeneck

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JUN 27 2000

TRANSMITTAL LETTER

Assistant Commissioner for Patents  
Washington, D.C. 20231

TECH 09/096,648/2900

Sir:

Transmitted herewith are a Supplemental Information Disclosure Statement and Statement of Information in Accordance with 37 C.F.R. § 1.56, cited references and PTO-Form 1449 (2 pages) for filing in connection with the above-identified application. Because this Supplemental Information Disclosure Statement is filed **after receipt of a First Office Action on the merits for the above-captioned application** but before either a Final Office Action or Notice of Allowance in the above-referenced application, the Commissioner is authorized to charge deposit account No. 50-1213, for the appropriate fee as stated below:

- ☒ The Commissioner is hereby authorized to charge any fee, that may be due in connection with this and the attached papers, or with this application during its entire pendency to or to credit any overpayment to Deposit Account No. 50-1213. A duplicate of this sheet is enclosed.

Respectfully submitted,  
HELLER, EHRMAN, WHITE & McAULIFFE

By: Paula K. Schoeneck  
Paula K. Schoeneck  
Registration No. 39,362

Attorney Docket No.: 24601-402A  
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE JUN 27 2000

Applicant: *HADLACZKY et al.*

Serial No.: 09/096,648

Filed: June 12, 1998

For: *ARTIFICIAL CHROMOSOMES,  
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6/19/00  
Date

*Paula Schoeneck*  
Paula Schoeneck



**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
IN ACCORDANCE WITH 37 C.F.R. §§ 1.97-1.98**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Because this Supplemental Information Disclosure Statement is filed after receipt of a First Office Action on the Merits for the above-captioned application, the Commissioner is authorized to charge the filing fee of \$230.00 or any fee that may be due in connection with this application during its entire pendency to Deposit Account No. 50-1213.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all references known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. The Forms PTO-1449 (2 pages) and copies of the cited documents are provided herewith.

The documents listed on the Forms PTO-1449 and supplied herewith are in the English language. In addition to the references indicated on the Forms PTO-1449 provided herewith, applicant makes known and provides copies of the following references: *Co et al.*, Generation of transgenic mice and germline

**U.S.S.N. 09/096,648**  
**HADLACZKY *et al.***  
**SUPPLEMENTAL IDS**

transmission of a mammalian artificial chromosome introduced into embryos by pronuclear microinjection, *Chromosome Research* 8:131-191, 2000; Calos, The potential of extrachromosomal replicating vectors for gene therapy, *TIG* 12(11):463-466 (1996); and, Verma I.M. and Somia N., Gene therapy, - promises, problems, and prospects, *Nature*, 389:239-242 (1997). The Calos and Verma references which have a publication date later than the priority date of the above-referenced application, were cited in a Form PTO-892 in copending application U.S.S.N. 08/835,682. The Co. *et al.* reference includes data that was presented in the Declaration of Perez pursuant to 37 C.F.R. §1.132 filed March 27, 2000. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items are necessary.

Applicant also makes known to the Examiner the recent status change of the following applications related by common ownership and/or inventorship to the above referenced application:

| <u>U.S.S.N.</u> | <u>Filing Date</u> | <u>Status</u>                                     |
|-----------------|--------------------|---|
| 08/695,191      | 08/07/96           | Issued on 2/15/00<br>as U.S. Pat. No. 6,025,155   |
| 08/682,080      | 07/15/96           | Issues on 06/20/2000<br>as U.S. Pat No. 6,077,697 |

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

**U.S.S.N. 09/096,648**  
**HADLACZKY *et al.***  
**SUPPLEMENTAL IDS**

Applicant respectfully requests that the Examiner review the foregoing references and that they be made of record in the file history of the above-captioned application.

Respectfully submitted,  
HELLER EHRMAN WHITE & McAULIFFE LLP

By:   
Paula K. Schoeneck  
Registration No. 39,362

Attorney Docket No. 24601-402A  
**Address all correspondence to:**  
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Hadlaczký *et al.*

Serial No.: 09/096,648

Filed: June 12, 1998

For: ARTIFICIAL CHROMOSOMES,  
USES THEREOF AND METHODS  
OF PREPARING ARTIFICIAL  
CHROMOSOMES

Art Unit: 1636

Examiner: Martin, J.



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Washington, D.C. 20231, on this date.

06/19/00  
Date

*Paula Schoeneck*  
Paula Schoeneck

**SUBMISSION OF INFORMATION IN ACCORDANCE WITH 37 C.F.R. § 1.56**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Any fees that may be due in connection with filing this paper may be charged to Deposit Account No. 50-1213.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Submission of Information in accordance with 37 C.F.R. §1.56.

The above-captioned application, which is a continuation of U.S. patent application Serial No. 08/629,822, designates as joint inventors: Gyula Hadlaczký and Aladar Szalay. Parent application U.S.S.N. 08/629,822 makes of record three assignees: (1) The Biological Research Center of the Hungarian Academy of Sciences for the joint inventor Gyula Hadlaczký, (2) Loma Linda University for any rights that joint inventor Aladar Szalay may have had an obligation to assign to Loma Linda University, and (3) American Gene Therapy,

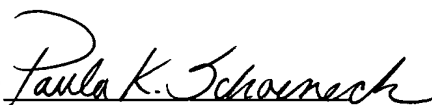
**U.S.S.N. 09/096,648**  
**HADLACZKY *et al.***  
**SUPPLEMENTAL IDS**

Inc. for any rights joint inventor Aladar Szalay may have possessed in the application. Subsequently, assignments were recorded in which American Gene Therapy, Inc. and Loma Linda University assigned any rights they may possess in the parent application to Chromos Molecular Systems, Inc. Thus the above-captioned application at present has two inventors and two owners, The Biological Research Center of the Hungarian Academy of Sciences, and Chromos Molecular Systems.

Applicant respectfully requests that the Examiner review the foregoing information and that it be made of record in the file history of the above-captioned application.

\* \* \*

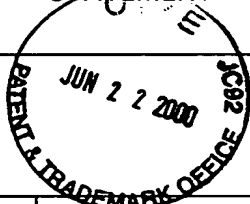
Respectfully submitted,  
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By:   
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Attorney Docket No. 24601-402A  
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EMAIL: sseidman@HEWM.com

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|--------------------------|--------------------------------------|--------------------------|
| FORM PTO-1449 (Modified) | ATTY. DOCKET NO.<br>24601-402A       | SERIAL NO.<br>09/096,648 |
|                          | APPLICANT<br>HADLACZKY <i>et al.</i> |                          |
|                          | FILING DATE<br>June 12, 1998         | GROUP<br>1632            |

LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S INFORMATION DISCLOSURE  
STATEMENT



## U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIAL | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB<br>CLASS | FILING<br>DATE |
|---------------------|-----------------|------|------|-------|--------------|----------------|
|                     |                 |      |      |       |              |                |
|                     |                 |      |      |       |              |                |
|                     |                 |      |      |       |              |                |

## FOREIGN PATENT DOCUMENTS

| DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB<br>CLASS | Translation |
|-----------------|------|---------|-------|--------------|-------------|
|                 |      |         |       |              |             |
|                 |      |         |       |              |             |
|                 |      |         |       |              |             |
|                 |      |         |       |              |             |

\* English language equivalent or Derwent abstract provided

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

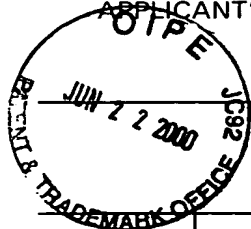
|    |  |
|----|--|
| AA | Vos JM, The simplicity of complex MACs, <i>Nature Biotechnology</i> 15:1257-1259 (1997)  |
| AB | Crystal, Transfer of Genes to Humans: Early Lessons and Obstacles to Success, <i>Science</i> 270:404-410 (1995).   |
| AC | Cuthbert <i>et al.</i> , Construction and characterization of a highly stable human:rodent monochromosomal hybrid panel for genetic complementation and genome mapping studies, <i>Cytogenet Cell Genet</i> 71:68-76 (1995). |
| AD | Garside <i>et al.</i> , A method for karyotyping mouse blastocyst embryos developing from in vivo and in vitro fertilized eggs, <i>Experientia</i> 41:1183-1184 (1985).  |
| AE | Higgins <i>et al.</i> , Organization of a repetitive human 1.8 kb KpnI sequence localized in the heterochromatin of chromosome 15, <i>Chromosoma</i> 93:77-86 (1985).  |
| AF | IJdo <i>et al.</i> , Improved telomere detection using a telomere repeat probe (TTAGGG) <sub>n</sub> generated by PCR, <i>Nucleic Acids Research</i> 19(17):4780 (1991).   |
| AG | Kalitsis <i>et al.</i> , A Chromosome 13-Specific Human Satellite I DNA Subfamily with Minor Presence on Chromosome 21: Further Studies on Robertsonian Translocations, <i>Genomics</i> 16:104-112 (1993).                   |
| AH | Klinger <i>et al.</i> , Modulation of the Activity of an Avian Gene Transferred into a Mammalian Cell by Cell Fusion, <i>Proc. Natl. Acad. Sci.</i> 71(4):1398-1402 (1974).  |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Modified)

ATTY. DOCKET NO.  
24601-402ASERIAL NO.  
09/096,648LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S INFORMATION DISCLOSURE  
STATEMENTAPPLICANT  
HADLACZKY *et al.*FILING DATE  
June 12, 1998GROUP  
1632

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

|    |   |
|----|---|
| AI | Larin <i>et al.</i> , <i>De novo</i> formation of several features of a centromere following introduction of a Y alphoid YAC into mammalian cells, <i>Human Molecular Genetics</i> 3(5):689-695 (1994).   |
| AJ | Ledbetter <i>et al.</i> , New Somatic Cell Hybrids for Physical Mapping in Distal Xq and the Fragile X Region, <i>American Journal of Medical Genetics</i> 38:418-420 (1991).                             |
| AK | Meyne <i>et al.</i> , Chromosome localization and orientation of the simple sequence repeat of human satellite I DNA, <i>Chromosoma</i> 103:99-103 (1994).  |
| AL | Rasko <i>et al.</i> , Pattern of segregation of chicken HPRT phenotype in Chinese hamster-chick red blood cell hybrids, <i>Cytogenet Cell Genet</i> 24:129-137 (1979).                                    |
| AM | Roberts <i>et al.</i> , Ribosomal RNA Gene Amplification: A Selective Advantage in Tissue Culture, <i>Cancer Genet Cytogenet</i> 29:119-127 (1987).   |
| AN | Sakai <i>et al.</i> , Human Ribosomal RNA Gene Cluster: Identification of the Proximal End Containing a Novel Tandem Repeat Sequence, <i>Genomics</i> 26:521-526 (1995).                                  |
| AO | Takeda <i>et al.</i> , Expression of SV40- <i>lacZ</i> Gene in Mouse Preimplantation Embryos After Pronuclear Microinjection, <i>Molecular Reproduction and Development</i> 30:90-94 (1991).              |
| AP | Thoraval <i>et al.</i> , A methylated human 9-kb repetitive sequence on acrocentric chromosomes is homologous to a subtelomeric repeat in chimpanzees, <i>Proc. Natl. Acad. Sci.</i> 93:4442-4447 (1996). |
| AQ | Vissel <i>et al.</i> , A satellite III sequence shared by human chromosomes 13, 14, and 21 that is contiguous with $\alpha$ satellite DNA, <i>Cytogenet Cell Genet</i> 61:81-86 (1992).                   |
| AR | Waye <i>et al.</i> , Human $\beta$ satellite DNA: Genomic organization and sequence definition of a class of highly repetitive tandem DNA, <i>Proc. Natl. Acad. Sci.</i> 86:6250-6254 (1989).             |
| AS | Worton <i>et al.</i> , Human Ribosomal RNA Genes: Orientation of the Tandem Array and Conservation of the 5' End, <i>Science</i> 239:64-68 (1988).  |

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